EXHIBIT 4

GIDEON, COOPER & ESSARY
A PROFESSIONAL LIMITED LIABILITY COMPANY
315 DEADERICK STREET, SUITE 1100
NASHVILLE, TENNESSEE 37238
(615) 254-0400
FAX (615) 254-0459
www.gideoncooper.com

C. J. GIDEON, JR.[1]
DIXIE W. COOPER[2]
BRYAN ESSARY[3]
CHRIS J. TARDIO[4]
CHRISTOPHER A. VRETTOS
ALAN S. BEAN
JAMES C. SPERRING
JOSHUA R. ADKINS
KIM J. KINSLER[5]
RANDA VON KANEL
J. BLAKE CARTER[1]
MARK A. HAMMERVOLD[1]
MATT H. CLINE
MATTHEW J. NATHANSON
JEREMY C. CAIN

[1]LICENSED IN TN & FL
[2]LICENSED IN TN, AL & TX
[3]LICENSED IN TN & GA
[4]LICENSED IN TN & KY
[5]LICENSED IN TN & WI

March 31, 2015

Via Email & U.S. Mail – lynn.marshall@fda.hhs.gov
Lynn M. Marshall
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: ***In re: New England Compounding Pharmacy, Inc., Products Liability Litigation Case No. 1:13-md-02419-RWZ***

Dear Ms. Marshall:

I am writing in response to your letter dated March 20, 2015, in which you objected to our subpoena for testimony and production of documents related to NECC and the 2012 meningitis outbreak.

At the outset of your letter, you noted that the requested testimony regards "a broad range of information going back at least thirteen years." Please keep in mind that the purpose of Fed. R. Civ. P. 30(b)(6) is to "streamline the discovery process" in civil litigation.[1] We are willing to work with the FDA to make this process as simple and efficient as possible. To that end, we propose a call to discuss these issues on April 10, 2015. Please let us know as soon as possible whether you are available.

Our healthcare provider clients purchased medication from NECC that turned out to be contaminated. The contaminated medication sickened patients. The Plaintiffs in multiple lawsuits have sued our clients, alleging that we should not have bought from a compounding pharmacy and specifically should not have bought from NECC. The Plaintiffs contend that the FDA advised against purchasing from compounding pharmacies.

[1] *QBE Ins. Corp. v. Jorda Enter., Inc.*, 277 F.R.D. 676 (S.D. Fla. 2012).

The Plaintiffs also contend that purchasing from an "FDA regulated" manufacturer of medication would have been *per se* safer than purchasing from a compounder, and that our clients should have known that the FDA was not exercising its enforcement power over NECC or other compounding pharmacies. These allegations against our clients make information and testimony from the FDA directly relevant to the claims against us.

Moreover, FDA testimony is appropriate in this case because the FDA coordinated investigations and enforcement against NECC with the Massachusetts Board of Pharmacy ("Mass. BoP") prior to the outbreak. Such information is directly relevant to the claim that, had our clients inquired of the FDA or Board of Pharmacy about the regulatory status of NECC, they would not have bought from NECC. The FDA also testified and produced documents to Congress regarding NECC and the meningitis outbreak, indicating knowledge of NECC that is not otherwise available to these Defendants, and is relevant to defense of the claims.[2]

All of these issues are relevant to the prosecution and defense of the claims against our clients. The Tennessee Clinic Defendants cannot adequately prepare and present their case without the requested deposition testimony and documents.

We address your specific concerns and objections below.

I. Statement to the Commissioner

You objected to our request for testimony because we have not submitted a written request to Commissioner Hamburg pursuant to 21 C.F.R. § 20.1. However, 21 C.F.R. § 20.1(c) states, in pertinent part:

> "If it is determined by the Commissioner, **or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose**, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto." (Emphasis added).

We had multiple conversations, both oral and by email, with Ms. DiPaola – *Senior Testimony Specialist* – to arrange service of this subpoena and notice. She instructed us to issue the subpoena and deposition notice directly to her. Ms. DiPaola's representations indicated she had been "designated to act on the Commissioner's behalf" for the purpose of receiving and responding to our request for testimony.[3]

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[2] *See A Continuing Investigation into the Fungal Meningitis Outbreak and Whether it Could Have Been Prevented*: Hearing Before the Subcomm. on Oversight and Investigations, 113th Cong. (2013) (statement of Margaret Hamburg, M.D., Commissioner of Food and Drugs, Food and Drugs Administration).

[3] Furthermore, federal courts have held that to the extent the FDA's regulations conflict with the Federal Rules of Civil Procedure, the regulations are invalid for exceeding the FDA's authority under 5 U.S.C. § 301, the federal "housekeeping" statute. *S.E.C. v. Selden*, 484 F. Supp. 2d 105, 108 (D.D.C. 2007);

It is rather disingenuous to invite the subpoena, agree to accept it, and now claim that a proper request was not made. Nevertheless, we will send a separate, notarized request for testimony to Commissioner Hamburg or whomever you designate if you insist that we do so.

* * * * * * * *

In your letter, you indicated that you require additional information to evaluate our request for deposition testimony. Below, we provide this supplemental information, tracking the requirements of 21 C.F.R. § 20.1.

1) Person's interest in the matter sought to be disclosed

We represent two surgical centers and several individual Tennessee health care providers (collectively "Tennessee Clinic Defendants") named as defendants in *In re: New England Compounding Pharmacy, Inc., Products Liability Litigation*, *Case No. 1:13-md-02419*. One-hundred and forty-three plaintiffs who received NECC's compounded methylprednisolone acetate ("MPA") have active lawsuits against our clients. These cases are currently before the United States District Court for the District of Massachusetts, where hundreds of cases against more than twenty (20) clinics from various states are consolidated into multi-district litigation for pre-trial matters.

NECC's bankruptcy proceeding is currently pending in the United States Bankruptcy Court for the District of Massachusetts.[4] Under 11 U.S.C. § 362(a)(1), NECC's bankruptcy petition operates as an automatic stay of the civil actions against it. Due to the stay, we have not been able to conduct any meaningful discovery of NECC.

The FDA's regulatory history with NECC, the enforcement actions the FDA took against NECC, and documents in the FDA's possession are highly relevant to our cases. The Plaintiffs' claims are based largely on the notion that the FDA warned against use of compounding pharmacies and the FDA did not regulate compounding pharmacies like NECC. The requested testimony and documents are indispensible for adequately preparing our cases for trial.

2) The use to which such testimony will be put in the event of compliance with such request

As a result of its bankruptcy proceeding, NECC is a nonparty in the Tennessee cases. However, Tennessee substantive law, which controls the cases against the Tennessee Clinic Defendants, permits apportionment of fault to immune nonparties.

The Tennessee Clinic Defendants intend to use the testimony and documents provided by the FDA to defend themselves in the lawsuits against them, including to assert comparative fault against NECC, the insolvent manufacturer that is to blame the

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Metrex Research Corp. v. United States, 151 F.R.D. 122, 124 (D. Colo. 1993) ("§20.1 is a regulation promulgated by FDA for its own benefit. It does not supersede the Federal Rules of Civil Procedure").

[4] *In re: New England Compounding, Inc., d/b/a New England Compounding Center. Case No. 12-19882.*

meningitis outbreak, and to prove the actions and inactions of the governmental agencies in regulating NECC.

3) How the testimony will be in the public interest

The meningitis outbreak caused by NECC's contaminated products is a matter of public health and safety. In Commissioner Hamburg's statement before the Subcommittee on Oversight and Investigations, she emphasized the "need for appropriate and effective oversight" of the evolving compounding industry.[5] Hundreds of patients in as many as twenty (20) states suffered fungal infections, meningitis, or death caused by NECC's contaminated products. Since the outbreak, the FDA has actively supported stronger laws and regulations so that it may take appropriate action against compounding pharmacies. By providing the testimony and documents requested by the Tennessee Clinic Defendants, the FDA will help facilitate the resolution of hundreds of cases in the MDL court, including those against the Tennessee Clinic Defendants. Additionally, disclosure of documents and testimony for use in the defense of the lawsuits will hopefully identify issues and problems with the FDA's regulation of compounding pharmacies, which is of public interest.

4) How such testimony will promote the objectives of the FDCA

The FDCA's primary purpose is to protect the public health of consumers. However, the FDCA and its legislative history make it clear that Congress intended the statute to protect the financial interests of consumers as well their health.[6] The FDA's deposition testimony and document production will expedite the litigation process and will likely encourage resolution of these cases by trial or settlement, in addition to further identifying issues and problems with compounding pharmacies.

II. 100-Mile Limitation Under Rule 45

When we first contacted the FDA about scheduling the 30(b)(6) deposition, we made clear that the proposed date and location for the deposition were tentative because we did not know whether an FDA representative from Nashville, Boston, or someplace else would testify.

We conferred several times with Ms. DiPaola to coordinate the deposition and minimize any inconvenience to the FDA. On February 26, 2015, Jeremy Cain from our office spoke with Ms. DiPaola via telephone. Ms. DiPaola agreed to accept service and was aware that we intended to issue the subpoena and notice for a deposition tentatively scheduled for April 3, 2015, in Nashville, but were more than happy to modify the subpoena to change the location.

On March 6, 2015, we issued the subpoena and notice to Ms. DiPaola for a 30(b)(6) deposition tentatively scheduled for May 4, 2015, providing the FDA with an

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[5] *See* Margaret Hamburg, M.D., *supra* note 2.

[6] *See United States v. Lane Labs-USA Inc.*, 427 F.3d 219, 227 (3d Cir. 2005); *see also United States v. An Article . . . Consisting of 216 Cartoned Bottles,* 409 F.2d 734, 740 (2d Cir. 1969) ("A primary purpose of the [FDCA] is the protection of the ultimate consumer's economic interests.")

additional month to designate its representative and to locate relevant documents in response to the subpoena *duces tecum*. The subpoena was based on both the information conveyed to us by Ms. DiPaola and on the good faith understanding that the FDA regularly transacts business within 100 miles of Nashville, Tennessee.[7]

Only after a government agency receives a notice for a Rule 30(b)(6) deposition does it designate its "officers, directors, or managing agents" to testify on its behalf.[8] Thus, at the time we issued the subpoena and deposition notice to you, it was impossible to know whether your designee "resides, is employed, or regularly transacts business in person" within 100 miles of Nashville, Tennessee.

Regardless of whether the "person" for purposes of Rules 45 and 30(b)(6) is the FDA as an organization or the actual witnesses you designate, we are happy to resolve this matter by modifying the subpoena we issued. We will agree to depose your designee within 100 miles of your headquarters in Rockville, Maryland, or any other mutually agreeable location.

III. FDA's Assertion of Various Privileges

You asserted several privileges in objection to producing requested documents, including trade secret, deliberative process privilege, attorney-client privilege, and the work-product doctrine.

These objections to *production* do not impact our ability to depose the FDA's designee under Rule 30(b)(6). Federal courts have reached this same conclusion. In *SEC v. Kramer,* the United States District Court for the Middle District of Florida noted that it is highly unusual to prohibit the taking of a deposition altogether absent extraordinary circumstances.[9] The *Kramer* court held that the need for protection usually cannot be determined before the examination begins, and that a party could move for a protective order if the need actually arises during a deposition.[10]

Regardless, if there are certain documents that the FDA contends must be withheld on account of privilege, a privilege log can be provided and potential objections to the assertion of privilege evaluated. Certainly, *all* documents responsive to the subpoena are not privileged.

IV. Objections to Overbreadth of Subpoena and Date of Production

You object to the subpoena on the ground that "it would take many hours of review and preparation for one or more FDA employees to become sufficiently versed" in the areas in which we seek testimony. Under federal precedent, this argument fails.

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[7] *See* FED. R. CIV. P. 45(c)(1)(A).
[8] FED. R. CIV. P. 30(b)(6).
[9] 778 F. Supp. 2d 1320, 1327 (M.D. Fla. 2011).
[10] *Id.* at 1327-28.

In *Connaught Labs., Inc. v. SmithKline Beecham P.L.C.*, the United State District Court for the District of Delaware ordered the FDA to comply with the defendant's subpoenas over the FDA's objection that requiring its employees to testify would create an undue burden on the FDA.[11] A government agency provided notice under Rule 30(b)(6) "has the duty to name and produce one or more persons who consent to testify on its behalf as to matters known or reasonably available to the organization."[12] The government must comply with reasonable requests for information even when such requests "will entail significant effort on the part of the United States."[13] Like any litigant, the government must abide by the Federal Rules of Civil Procedure.[14]

The FDA has already produced documents to, and testified before, Congress related to the meningitis outbreak. Reproducing these previously-produced documents will not be unduly burdensome on the FDA. Additionally, in our *duces tecum*, we instructed that, to the extent requested documents have already been produced or are publicly available, you may simply state that to be the case and point us to where the documents are housed.

Under the Deposition Protocol that governs these cases, a party noticing a deposition pursuant to Rule 30(b)(6) must provide at least thirty (30) days notice to allow time for the identification and preparation of the person(s) designated to testify on the noticed topics. By issuing the subpoena and deposition notice on March 6, 2015 for a deposition tentatively scheduled for May 4, 2015, we provided sufficient notice that is nearly double the required amount of time under the Protocol. Moreover, common issue discovery for all MDL cases must be completed by June 15, 2015. Thus, while we are willing to work with the FDA on the timeframe, we must do so within the deadlines of our scheduling order.

V. Proposed Solution

We propose that we should resolve your objections to the 30(b)(6) deposition separately from your assertion of privilege over certain requested documents. If the only obstacles to taking the deposition are (1) the need for a separate statement to the Commissioner pursuant to 21 C.F.R. § 20.1 and (2) a subpoena for testimony within 100 miles of Rockville, Maryland (or another mutually agreeable location), we can easily address those objections.

Regarding your objections to document production and assertion of privilege, we propose a phone conference at your earliest convenience to discuss and resolve these issues. We proposed a conference call on Tuesday, March 17, 2015, but did not receive confirmation from you. As noted above, please let us know your availability on April 10.

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[11] 7 F. Supp. 2d 477, 480 (D. Del. 1998).
[12] *United States v. Magnesium Corp. of Am.*, No. 2:01-CV-40DB, 2006 U.S. Dist Lexis 87734 (D. Utah Nov. 27, 2006), at *15-16.
[13] *Id.*
[14] *SEC v. Collins & Aikman Corp.*, 256 F.R.D. 403, 414 (S.D.N.Y. 2009).

Thank you.

Sincerely,

Chris J. Tardio

Cc: Lauren DiPaola
C. J. Gideon, Jr.
Matt Cline
Jeremy Cain